REMARKS

Claims 11, 12, 17, 20-22, 24, and 27-32 are pending in the current application. Claims 11, 12, 17, 24, 28, 29, 30, 31, and 32 have been amended, leaving Claims 11, 12, 17, 20-22, 24, and 27-32 for consideration upon entry of the present amendment.

Support for the amendment to Claim 11 can be found on Page 2, lines 9-17 of the Specification as originally filed.

Support for the amendment to Claims 12 and 31 may be found in the claims themselves.

Support for the amendment to Claim 17 can be found on Page 2 of the Specification as originally filed.

Support for the amendment to Claim 24 may be found in the claim itself.

Support for the amendment to Claims 28, 29, 30 and 32 reciting an upper respiratory disorder can be found in the Abstract and in the 3rd full paragraph on page 2 of the Substitute Specification mailed on September 23, 2002 as amended herein.

Support for the amendments to Claims 28 and 30 can be found on Page 2, lines 9-17 of the Specification as originally filed.

Support for the amendments to the 2nd full paragraph on page 2 of the Substitute Specification can be found in on page 2, lines 9-17 of the Specification as originally filed.

Support for the amendment to the 3rd full paragraph on page 2 of the Substitute Specification mailed on September 23, 2002 can be found in the Abstract of the Application as filed.

No new matter has been introduced by these amendments.

Objections Under 35 U.S.C. § 132

The Examiner objects to the material presented in the amendment filed on March 3, 2003 stating that the amendment added material which is not supported by the original disclosure. Applicants note that the "4" in 104 was stricken out but did not show up as such in the amendment. The Specification has been amended to clarify the change and also for consistency with Claim 11. Claim 11 has been re-amended to recite the 4 vol% limitation. Reconsideration and withdrawal of the claim objections are requested.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 28-32 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner alleges that there is no support in the Specification as filed for "upper respiratory infection". The Specification and Claims 28 and 30 have been amended to recite "upper respiratory disorder" as stated in the Abstract of the Application as filed. Applicants submit that the Abstract and the amended Specification fully support Claims 28 and 30 and the Claims that depend therefrom. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, are requested.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 12, 17, 20-22, 24, and 27-32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

In particular, the Examiner states that the recitation of "balanced mixtures" is not understood (Paper 12, Page 2). Claims 28 and 12 have been amended to recite "a mixture" as suggested by the Examiner. Claim 31 has also been amended in the same manner.

The Examiner also states that the term "or a fine powder" in Claim 24 is in improper Markush language. Claim 24 has been amended to recite "and a fine powder" as suggested by the Examiner.

Regarding Claims 29 and 32, the Examiner states that the recitation of "wherein the upper respiratory infection results in sinusitis or rhinitis" is not clear. Claims 29 and 32 have been amended to recite "wherein the upper respiratory disorder is sinusitis or rhinitis" as suggested by the Examiner.

The Examiner further states that the term "nasal releaser" in Claim 17 is colloquial. Claim 17 has been amended to recite "used to exfoliate the mucosa of the nasal passages" as suggested by the Examiner.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, are requested.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 11-25 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over DE 2721014 to Reith (hereinafter "Reith"). Applicants respectfully traverse this rejection.

The present claims are directed to a method of treating sinusitis and rhinitis in a human or an animal in need thereof, the method comprising administering to a nasal passageway of the human or the animal a composition comprising alpha-hydroxypropionic acid and a pharmaceutically acceptable vehicle, wherein the alpha-hydroxypropionic acid is in a concentration of 0.2-4 vol.% based on the volume of the acceptable pharmaceutical vehicle. Also claimed are similar methods of treating an upper respiratory disorder by administering the same composition to a nasal passageway. All of the present claims share the feature of administration to a nasal passageway.

Reith teaches the use of lactic acid (i.e., alpha-hydroxypropionic acid) to treat allergies and viral diseases. Reith further teaches the lactic acid in the form of tablets, dragees or capsules.

The present Application claims a method comprising administering a composition comprising alpha-hydroxypropionic acid and a vehicle to a nasal passageway. First, Reith does not teach administration of alpha-hydroxypropionic acid to a nasal passageway. Reith teaches only the oral administration of alpha-hydroxypropionic acid in the form of tablets, dragees, and capsules. Second, Reith does not teach alpha-hydroxypropionic acid in a concentration of 0.2-4 vol.% based on the volume of the acceptable pharmaceutical vehicle. Because Reith does not address nasal administration of alpha-hydroxypropionic acid, Reith cannot teach the dosage concentration of alpha-hydroxypropionic acid useful for nasal administration. Thus, there are elements of the present claims that are not taught by Reith.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled

artisan to modify a reference or combined references; and that the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was make. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Reith fails to teach nasal administration of alpha-hydroxypropionic acid and also fails to teach the presently claimed amounts of the alpha-hydroxypropionic acid. Reith thus fails to teach all elements of the present claims.

In addition, because Reith teaches only oral administration of the alpha-hydroxypropionic acid, Reith cannot provide the motivation for nasal administration of alpha-hydroxypropionic acid or the dosage amounts suitable for such administration. Reith further does not provide an expectation of success for nasal administration. As is known in the pharmaceutical arts, not all routes of administration are suitable for all active agents. The disclosure of oral administration as in Reith does not provide the motivation or expectation of success for other means of administration such as the presently claimed nasal administration.

Regarding the presently claimed dosage forms, the Examiner has alleged that once a method of use of a compound is known, "it would be obvious to one of ordinary skill in the art to determine the optimum amount of active agent and the vehicle system" (Paper 12, Page 3). Applicants disagree. First, applicants maintain that Reith does not teach the same method of use as Reith does not teach a method for treating sinusitis and rhinitis. Second, Reith teaches only oral administration and not nasal administration of alpha-hydroxypropionic acid. Third, because Reith does not teach nasal administration of alpha-hydroxypropionic acid, Reith cannot teach the dosages that are optimal for nasal administration because Reith does not teach nasal administration. There is no expectation based on the teachings of Reith that alpha-hydroxypropionic acid is suitable for treatment of sinusitis and rhinitis or for nasal administration or that the claimed amounts would be optimal for nasal administration.

Regarding the first point, Applicants maintain that Reith does not teach the same method of use as is presently claimed. Reith teaches a method of treating allergies and viral diseases. While sinusitis and rhinitis can be manifestations of allergies and some viral diseases as maintained by the Examiner, there is no teaching or suggestion that it is these

manifestations that the alpha-hydroxypropionic acid is expected to improve. Because there is no teaching in Reith of the treatment of sinusitis and rhinitis, there is certainly no teaching of the treatment of these conditions in the absence of allergies or a viral disease. As pointed out in the present Application, sinusitis, for example, can be caused by pathogenic bacteria and yeast. There is no teaching or suggestion in Reith that alpha-hydroxypropionic acid is useful for treatment of sinusitis associated with bacteria and/or yeast. The method of use as presently claimed is a general method to treat sinusitis and rhinitis regardless of their etiology, while Reith is directed only to treating allergy and viral diseases. Applicants thus maintain the Reith does not teach the presently claimed method.

Second, Reith teaches only oral administration of alpha-hydroxypropionic acid for the treatment of allergies and viral diseases. Reith further does not specifically teach the use of administration of alpha-hydroxypropionic acid specifically for the respiratory manifestations of these conditions such as sinusitis and rhinitis. There is thus no motivation or suggestion in Reith that nasal administration would be a desirable or feasible route for administration of alpha-hydroxypropionic acid. Not all routes of administration are suitable for all active agents. The disclosure of oral administration by Reith does not render the presently claimed nasal administration obvious.

Third, because Reith does not teach nasal administration of the administration of alpha-hydroxypropionic acid, it cannot teach the dosage amount that is suitable for nasal administration. In fact, the abstract and claims of Reith do not disclose any dosage amounts. There is no teaching in Reith that would teach one how to formulate a dosage form suitable for nasal administration. Simply because an active agent is known, it is not known which dosage amount is suitable for every application and every route of administration. Thus, Reith does not render obvious the presently claimed dosage amounts for nasal administration.

Regarding Claims 27-32, the Examiner makes similar arguments regarding the use of administration of alpha-hydroxypropionic acid. Claims 27-32 are directed to methods of treatment of upper respiratory disorders by nasal administration of alpha-hydroxypropionic acid. To treat upper respiratory diseases. As with sinusitis and rhinitis, there is no teaching in Reith that administration of alpha-hydroxypropionic acid is suitable for the upper

respiratory manifestations of allergies and viral diseases. The same arguments regarding the method, nasal administration, and dosage amounts apply to these claims.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are requested.

In light of the foregoing amendments and remarks, reconsideration by the Examiner is respectfully requested. It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Cantor Colburn LLP.

Respectfully submitted,

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